

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**



**CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment
November 17-18, 2008
Bethesda, Maryland**

Record of the Proceedings

TABLE OF CONTENTS

	<u>Page</u>
Attachment 1: List of Participants.....	A1-1
Attachment 2: Acronyms Used in These Meeting Minutes.....	A2-1
Meeting Minutes.....	1
November 17, 2008	
Opening Session.....	1
HRSA Administrator’s Report.....	2
NCHHSTP Director’s Report.....	3
Overview of CDC’s Revised U.S. HIV Incidence and Prevalence Estimates.....	9
Update by the CHAC Ryan White Reauthorization Workgroup.....	13
Update on HRSA’s HIV Workforce Activities.....	15
Update on HAB Quality Measures.....	17
 November 18, 2008	
Panel Presentation on the Mental Health Services-HIV/STD Interface.....	19
Overview of the Bureau of Primary Health Care.....	24
Panel Presentation on ART Resistance in International Settings.....	28
CHAC Business Session.....	32
Public Comment Session.....	35
Closing Session.....	35
Appendix I: Statements Submitted Into the Public Record.....	37

ATTACHMENT 1

List of Participants

Current and Outgoing CHAC Members

Dr. Edward Hook III, Co-Chair
Dr. Donna Sweet, Co-Chair
Dr. Bruce Agins
Ms. Renee Austin
Dr. William Cunningham
Ms. Theresa Devlin
Ms. Evelyn Foust
Dr. Fernando Garcia
Rev. Debra Hickman
Ms. Antigone Hodgins
Ms. Maria Lago
Mr. Thomas Liberti
Mr. Harold Phillips
Dr. Andrè Rawls
Dr. Lydia Temoshok
Dr. Nathan Thielman
Ms. Lisa Tiger
Dr. Carmen Zorrilla

CHAC Ex-Officio Representatives

Dr. Pradip Akolkar
(Food and Drug Administration)
Dr. Scott Giberson (Indian Health Service)
Dr. William Grace
(National Institutes of Health)

Designated Federal Officials

Dr. Elizabeth Duke
Administrator, HRSA
Dr. Kevin Fenton
NCHHSTP Director, CDC

HHS, CDC and HRSA Representatives

Dr. Barbara Aranda-Naranjo
Mr. Christopher Bates
Dr. Geoff Beckett
Dr. Chris Cagle
Dr. Laura Cheever
Dr. John Douglas, Jr.
Ms. Teresa Durden
Mr. Michael Evanson
Dr. Kaytura Felix

Dr. Christopher Gordon
Ms. Shelley Gordon
Dr. Deborah Parham Hopson
Dr. Elizabeth Lopez
Ms. Faye Malitz
Ms. Sheila McCarthy
Dr. Jose Morales
Mr. Douglas Morgan
Dr. Jeffrey Nadler
Ms. Amy Pulver
Ms. Ilze Ruditis [via conference call]
Dr. Marc Safran
Ms. Margie Scott-Cseh
Ms. Traci Sears
Ms. Adelle Simmons
Dr. Heather Watts
Dr. Howell Wechsler
Dr. Richard Wolitski
Mr. Steven Young

Guest Presenters and Members of the Public

Ms. Deborah Arrindell
(American Social Health Association)
Ms. Stephanie Craig (Northwest Portland
Area Indian Health Board)
Dr. Jennifer Joseph (National Association
of County and City Health Officials)
Dr. Peter Kerndt
(National Coalition of STD Directors)
Ms. Ann Lefert (National Alliance of
State and Territorial AIDS Directors)
Dr. Peter Leone
(National Coalition of STD Directors)
Ms. Kim Loe
(Infectious Disease Society of America)
Mr. Carlos Soles (Office of Minority Health
Resource Center)
Mr. Chris Stoughton (Pacific Institute for
Research and Evaluation)
Ms. Ogochukarn Umejei
(Indian Health Service)
Ms. Julie Willig (AIDS Action)

ATTACHMENT 2

Acronyms Used in These Meeting Minutes

AAs	— African Americans
ADAP	— AIDS Drug Assistance Program
AI/AN	— American Indians/Alaska Natives
API	— Asian/Pacific Islanders
ART	— Antiretroviral Therapy
ASHA	— American Social Health Association
AZT	— Azidothymidine
BPHC	— Bureau of Primary Health Care
CDC	— Centers for Disease Control and Prevention
CHAC	— CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
CHCs	— Community Health Centers
CMHS	— Center for Mental Health Services
DEBI	— Diffusion of Effective Behavioral Interventions
DFO	— Designated Federal Official
DHAP	— Division of HIV/AIDS Prevention
DSTDTP	— Division of STD Prevention
DVH	— Division of Viral Hepatitis
EMAs	— Eligible Metropolitan Areas
EWI	— Early Warning Indicator
FAPP	— Federal AIDS Policy Partnership
FAQs	— Frequently Asked Questions
FOAs	— Funding Opportunity Announcements
FQHCs	— Federally Qualified Health Centers
GAP	— Global AIDS Program
HAART	— Highly Active Antiretroviral Therapy
HAB	— HIV/AIDS Bureau
HBV	— Hepatitis B Virus
HCV	— Hepatitis C Virus
HHS	— Department of Health and Human Services
HIVDR	— HIV Drug Resistance
HNI	— Healthiest Nation Initiative
HRSA	— Health Resources and Services Administration
IDUs	— Injection Drug Users
IOM	— Institute of Medicine
JAMA	— <i>Journal of the American Medical Association</i>
MAI	— Minority AIDS Initiative
MHHSC	— Mental Health HIV Services Collaborative
MH/SA	— Mental Health/Substance Abuse
MMWR	— <i>Morbidity and Mortality Weekly Report</i>
MSM	— Men Who Have Sex With Men
MTCT	— Mother-to-Child Transmission
NCHHSTP	— National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCSD	— National Coalition of STD Directors
NIH	— National Institutes of Health

NIMH	—	National Institute of Mental Health
NVP	—	Nevirapine
PCSI	—	Program Collaboration and Service Integration
PEPFAR	—	President's Emergency Plan for AIDS Relief
PSAs	—	Public Service Announcements
SAMHSA	—	Substance Abuse and Mental Health Service Administration
SONI	—	Severity of Need Index
SPNS	—	Special Projects of National Significance
TRP	—	Therapeutics Research Program
WHO	—	World Health Organization

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Minutes of the Meeting

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and Health Resources and Services Administration (HRSA) convened a meeting of the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC). The proceedings were held at the Bethesda North Marriott Hotel & Conference Center in Bethesda, Maryland on November 17-18, 2008.

Opening Session

Drs. Edward Hook III and Donna Sweet, co-Chairs of CHAC, called the meeting to order at 8:30 a.m. on November 17, 2008 and welcomed the attendees to the proceedings. They particularly recognized the new CHAC members: Ms. Antigone Hodgins, Mr. Ernest Hopkins, and Drs. William Cunningham, Carlos del Rio, Jose Esparza, Jeanne Marrasso, Kenneth Mayer and Andrè Rawls. The list of participants is appended to the minutes as [Attachment 1](#).

Dr. Kevin Fenton, Director of the CDC National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) and the CHAC Designated Federal Official (DFO) for CDC, reminded the participants that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. He advised CHAC members to be mindful of potential conflicts of interest identified by the CDC or HRSA Committee Management Office and to recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict of interest.

Dr. Fenton presented certificates of appreciation to four outgoing members who represented CDC during their respective tenures on CHAC: Theresa Devlin, Aaron Shirley, Lydia Temoshok and Nathan Thielman. The participants applauded the outstanding service and contributions of the four outgoing CHAC members.

Dr. Elizabeth Duke, Administrator of HRSA and the CHAC DFO for HRSA, presented certificates of appreciation to four outgoing members who represented HRSA during their respective tenures on CHAC: Renee Austin, Fernando Garcia, Thomas Liberti and Carmen Zorrilla. The participants applauded the outstanding service and contributions of the four outgoing CHAC members.

Dr. Sweet entertained a motion for CHAC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Mr. Liberti and Dr. Zorrilla, respectively, for CHAC to adopt the previous meeting minutes. CHAC **unanimously approved** the "Draft May 20-21, 2008 Meeting Minutes" with no changes or discussion.

HRSA Administrator's Report

Dr. Duke covered the following areas in her update. HRSA's agency-wide mission to serve medically underserved populations is the foundation for all of its activities in all bureaus and offices. HRSA's mission is particularly important for the HIV/AIDS Bureau (HAB) because 27% of clients in the Ryan White HIV/AIDS Program have no insurance and 57% live below the poverty level. As a result, HRSA recognizes the importance and critical need of HAB's services.

HRSA is organizationally structured as an integrated set of programs to focus on medically underserved populations. The overarching mission of HRSA Community Health Centers (CHCs) is to provide primary and preventive care, but 91% of CHCs also offer onsite HIV testing and counseling. All HRSA bureaus and offices are full partners in the agency-wide effort on HIV/AIDS.

CHAC previously asked HRSA to identify disruptions in care and other challenges associated with the implementation of core medical services of the reauthorized Ryan White Program. CHAC also asked HRSA to determine the impact of Ryan White funding on service delivery for grantees. HRSA responded to CHAC's requests by conducting studies on the impact of policy changes related to Ryan White reauthorization and eligibility determination. HRSA will post the findings of these studies on its web site in December 2008 and September 2009.

HRSA will publish a *Federal Register* notice to obtain public comments on its client-level data system. In the interim, however, HRSA has posted information on its web site on data collection and reporting needs for 2009 and also will provide technical assistance to grantees on the client-level data system.

HRSA used FY'08 Special Projects of National Significance (SPNS) dollars to award funding to 17 Parts A and B grantees to help build the health information technology infrastructure and enhance the client-level data system. HRSA will use FY'09 dollars to make similar awards to Parts C and D grantees. HRSA expects to have a fully operational and integrated system by the end of 2009.

HRSA is continuing its collaborations with federal partners. HRSA and the Federal Interagency HIV/AIDS Committee jointly published *Recommendations on Case Management Collaboration and Coordination in Federally-Funded HIV/AIDS Programs*. The guidance offers strategies to provide linkages and coordinate efforts between case management programs and the federal sector. HRSA has an interagency agreement to conduct testing and training through its AIDS Education and Training Centers. The broad-scale training program will be evaluated to determine its impact and the findings will be posted on the HRSA web site.

CHAC was well represented at the all-grantee meeting in August 2008. CHAC's meetings with grantees played a significant role in HRSA's efforts to share policy and clinical information with its grantees. HRSA will convene another all-grantee meeting in 2010.

HRSA is continuing to conduct a number of activities under its Global AIDS Initiative. Funding from the President's Emergency Plan for AIDS Relief (PEPFAR) has allowed HRSA to become the third largest global funder of AIDS. HRSA is applying its domestic HIV/AIDS experience to ensure that excellent care, treatment, data collection and evaluation are provided internationally.

HRSA is sharing its electronic CAREWare health information system with international partners to track Ryan White program clients at the global level. The system is currently being used or is planning to be used to manage patient records in Nigeria, Uganda, Hanoi, Honduras, Panama and Russia.

In terms of the transition, Dr. Duke confirmed that HRSA has gathered solid data and compiled numerous options on the Ryan White Program to present to the new HHS Secretary in an effort to address the priorities of the new Administration.

NCHHSTP Director's Report

Dr. Fenton covered the following areas in his update. CDC is a member of the Healthiest Nation Alliance. This group of individuals and organizations represents local, state, national and international perspectives and has made a commitment to collaborate in taking decisive actions to accelerate true improvements in health across America. At this time, >500 organizations and individuals have joined the Healthiest Nation Alliance.

Under the Healthiest Nation Initiative (HNI), CDC intends to catalyze a self-sustaining, primarily externally resourced and broad-based U.S. movement to accelerate health protection, improve health equity and enhance the value of health investments. The HNI is based on six key strategies: expand the vision, empower leaders, energize individuals, enact health in all policies, execute health protection goals and evaluate health.

CDC has launched a number of specific activities to support the HNI. CDC's Health Protection Goals are high-level and cross-cutting strategic priorities that focus on four key domains: healthy people, healthy places, preparedness, and healthy people in a healthy world. CDC

established and will soon implement 14 areas of activities for health protection priorities under the four key domains.

CDC created lifestyle centers, developed garden markets and is exploring telecommuting options for its employees. "Go Green, Get Healthy" is an internal CDC initiative to promote a greener and healthier agency. CDC's green activities include green vendor fairs, green purchasing and training, enhanced recycling and green tips on the Intranet.

The general public and organizations can participate in the HNI by supporting the need for America to become a healthiest nation and improve the value of health investments; taking at least one specific action to improve health and model positive health behavior in homes, schools, communities, organizations or jurisdictions; informing others about personal efforts and their impacts; encouraging others to take the same action; and joining the Healthiest Nation Alliance at www.healthiestnation.org.

The NCHHSTP divisions accomplished several goals in FY'08. The Division of HIV/AIDS Prevention (DHAP) published HIV incidence estimates from CDC's first national incidence surveillance system in the *Journal of the American Medical Association (JAMA)* in August 2008. All states, the District of Columbia and five territories have adopted confidential, name-based reporting.

DHAP held the first Latino consultation in its continued effort to strengthen prevention programs for minority communities. HIV prevention efforts for men who have sex with men (MSM) were enhanced through additional interventions and tools. The *Compendium of Effective Interventions* was updated. The one-year anniversary of the "Heightened National Response to the HIV/AIDS Crisis in the African American Community" was commemorated during a meeting DHAP held in May 2008 with both existing and new partners.

The Division of STD Prevention (DSTDP) collaborated with DHAP to publish partner services guidelines for HIV, syphilis, gonorrhea and chlamydia infection in the November 7, 2008 edition of the *Morbidity and Mortality Weekly Report (MMWR)*. The integrated guidance for STDs and HIV partner services was aimed at health department managers, highlighted the importance of partner services, and emphasized the critical need for program collaboration and service integration (PCSI) in partner services.

DSTDP released new estimates that showed one in four female adolescents in the United States has at least one of the most common STDs. The "Safe in the City" HIV/STD prevention video for STD clinics was found to be effective in reducing new infections among STD clinic patients. National guidelines were released for Internet-based STD/HIV prevention activities.

The Division of Viral Hepatitis (DVH) published new recommendations for the identification and public health management of persons with chronic hepatitis B virus (HBV) infection. The guidance calls for routine testing of persons born in Asia, Africa and other regions with at least 2% greater prevalence of chronic HBV infection; MSM and injection drug users (IDUs); persons

with abnormal liver function not explained by other factors; and persons with selected medical conditions who require immunosuppressive therapy.

DVH investigated a cluster of hepatitis C virus (HCV) infections in Nevada and linked these infections to unsafe injection practices at an endoscopy clinic. The Adult Viral Hepatitis Coordinator Program was expanded to most states for CDC to provide support in leveraging resources for viral hepatitis prevention at the local level. The World Health Organization (WHO) designated DVH as a Collaborating Center for Reference and Research on viral hepatitis prevention through 2012.

DVH collaborated with internal CDC partners to promote and accelerate adult HBV vaccination activities. CDC awarded \$20 million of Section 317 funds in FY'07 to 51 state and local health departments to purchase HBV vaccine to immunize high-risk adults. At this time, 1,500 settings are participating in this effort. The program will be continued for a second year with \$16 million to purchase additional vaccine to further promote HBV elimination in the United States.

The Global AIDS Program (GAP) partnered with Ministries of Health and U.S. government colleagues to inform the PEPFAR reauthorization process. The President signed the "Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, TB and Malaria Reauthorization Act" into law on July 30, 2008. The legislation will authorize up to \$48 billion over the next five years and increase the U.S. financial commitment to the fight against global HIV/AIDS, TB and malaria.

Specific allocations of the PEPFAR II appropriation include (1) \$39 billion for PEPFAR bilateral HIV/AIDS programs and U.S. contributions to the Global Fund to fight AIDS, TB and malaria; (2) \$5 billion to the President's Malaria Initiative to fight malaria through bilateral programs around the world; and (3) \$4 billion to bilateral programs to fight TB due to its role as the leading killer of Africans living with HIV.

In PEPFAR I, 1.73 million men, women and children received antiretroviral therapy (ART); 12.7 million pregnant women participated in the prevention of mother-to-child transmission (MTCT) of HIV; and 194,000 HIV infant infections were prevented. The ten-year program goals of PEPFAR II will be to treat at least 3 million HIV-infected persons; prevent 12 million new HIV infections; provide care for 12 million HIV-infected persons, including 5 million orphans and vulnerable children; strengthen health systems; improve systems to promote monitoring and evaluation of activities; and train at least 140,000 new healthcare providers.

The NCHHSTP Office of the Director is continuing its PCSI activities and took a number of actions in response to three FY'08 priorities that were identified during the PCSI consultation in August 2007. For "integrated funding," NCHHSTP included PCSI language in four of 11 non-research cooperative agreements and other new funding opportunity announcements (FOAs). The site visit to Indian Country led to NCHHSTP including stronger policy language on PCSI in one of 11 FOAs and making a commitment to support Native-oriented prevention programs in future FOAs.

For “integrated training,” NCHHSTP held a meeting with funded training partners in June 2008 and developed a meeting report outlining next steps and recommendations to enhance PCSI training. NCHHSTP made site visits to jurisdictions across the country and Indian Country to explore opportunities to strengthen PCSI at the local level. For “integrated surveillance,” the Cross-Center Workgroup is exploring shared confidentiality assurance tools for NCHHSTP programs and plans to publish recommendations on this issue in FY’09. NCHHSTP published its first integrated surveillance report.

NCHHSTP is continuing to focus on its cross-cutting priority of health disparities. The FY’08 *Health Disparities Report* highlighted 92 domestic projects the divisions are conducting to address health disparities and social determinants of health related to NCHHSTP’s diseases. NCHHSTP completed its report to HHS on White House initiatives for racial/ethnic minorities.

NCHHSTP is using new and creative media to deliver HIV prevention messages. NCHHSTP trained college students on HIV prevention messaging and provided tools to the students to develop videos, public service announcements (PSAs) and peer messages on HIV testing. PSAs developed by the students were posted on the CDC web site, You Tube and other social networking media. NCHHSTP collaborated with partners to launch “short message service” texting in a social media cross-promotion campaign. This initiative allows persons to obtain the location of the nearest HIV or STD screening site by texting their zip codes to “KNOWIT.”

NCHHSTP developed new tools to improve its communications with partners. The *Connections* newsletter has >8,000 subscribers and received tremendously positive feedback from readers. The CDC web site was updated to include a PCSI web page and a portal for NCHHSTP prevention partners. The “GovDelivery” service allows subscribers to copy messages from the CDC web site to their personal e-mail inboxes. Over the past ten months, 8,600 persons have subscribed to the service.

The NCHHSTP web site received 756,000 Internet/Intranet views from January-August 2008. NCHHSTP topics accounted for ~36% of search terms entered into the CDC.gov Google engine and ~33% of the top 100 web pages viewed on CDC.gov. STD, HIV, hepatitis and TB were the 1st, 10th, 14th and 16th most popular topics, respectively, viewed on CDC.gov in 2007-2008.

Drs. Fenton and Julie Gerberding, Director of CDC, testified before the House Oversight and Government Reform Committee in September 2008 on “HIV/AIDS in the United States: A Look Back and a Look Forward.” Drs. Fenton and Gerberding described actions that would need to be taken to achieve bold HIV reductions in the United States. The testimony is posted on the Committee’s web site.

NCHHSTP complied with the Ryan White HIV/AIDS Treatment Modernization Act of 2006 by implementing an Early Diagnosis Grant Program in FY’08. NCHHSTP re-competed the HIV Incidence Program and Comprehensive STD Prevention Systems FOAs. Mississippi and Texas were added to the HIV testing initiative. CDC is operating under a continuing resolution that will extend government operations through March 6, 2009 and provide continued funding at FY’08

levels. NCHHSTP appointed a new Associate Director for Program Integration and expects to appoint a permanent DHAP Director in the near future.

Drs. Fenton and Richard Wolitski, Acting Director of DHAP, provided additional details on NCHHSTP's prevention activities in response to CHAC's specific questions and comments.

- CDC will explore strategies to address CHAC's suggestion to move beyond the historical silo approach. For example, CDC could sponsor joint interagency meetings and other activities to focus on the full spectrum of care and prevention. The development of a National HIV Plan for the United States would play a key role in promoting collaboration across sectors as well.
- CDC closely collaborated with and provided recommendations to HHS on PEPFAR II language that proposed removing the ban on immigration to the United States based on HIV positive status. HHS has made a commitment to address this issue as quickly as possible, but the methodology that will be used to develop new rules would probably require wide external consultation prior to implementation.
- PEPFAR II contains specific language to provide more support for operational research, including evaluation, primary research, and health systems research to improve and better understand service quality and delivery. The U.S. government recognizes the critical need for these activities to assess the progress of PEPFAR prevention programs; compile lessons learned that could have implications for prevention programs in the United States and developing countries; and incorporate continuous quality improvement into PEPFAR prevention programs, particularly clinical care in resource-poor countries. Federal partners are currently attempting to agree on a PEPFAR operational research agenda and identify specific roles and responsibilities in this effort. In addition to the operational research agenda, key priority areas of PEPFAR II also will include capacity building and development of a stronger workforce; enhancement of training programs for healthcare providers and para-professionals; expansion of the HIV prevention, treatment and care model to chronic diseases; and application of regional solutions in resource-poor settings.
- CDC is continuing its national dialogue with Congress, political leaders and federal partners to raise the profile of prevention. CDC is taking a more comprehensive prevention approach by improving its prevention toolkit with better research and culturally competent interventions; scaling-up effective prevention interventions to have a greater impact; and implementing a more holistic strategy by focusing on the acceleration of HIV transmission through the STD, hepatitis and TB syndemics. CDC will continue to demonstrate the effectiveness of HIV testing and other prevention activities.
- CDC is conducting several prevention activities to meet the needs of Hispanics/Latinos in the United States including: strengthening the collection and use of surveillance data; conducting research to develop and evaluate existing and new interventions; building

programmatic capacity; and enhancing communications through newsletters and web site notices. CDC has made a commitment to further develop and implement prevention programs in close partnership with the Latino community to have the greatest impact. CDC formed a Latino Executive Committee that has developed and will release an action plan for this population over the next few weeks. The action plan will provide recommendations on CDC's existing and future prevention activities for the Latino community.

- DHAP is allocating the bulk of its resources and targeting the majority of its prevention efforts at the division level to three priority populations: MSM in all racial/ethnic groups, African Americans (AAs) and Latinos.
- CDC is aware of the increased demand for surveillance at state and local levels and the need to enhance technical capacity of staff in this area. CDC is taking three key actions to respond to state and local surveillance needs: (1) exploring strategies to strengthen national surveillance programs; (2) establishing a budget to modernize surveillance systems; and (3) attempting to leverage funds from HRSA and other federal partners to support surveillance of disease epidemiology, treatment and care. However, HRSA informed CDC that Ryan White dollars could not be used for surveillance to count actual HIV/AIDS cases in states.
- CDC will soon publish its goal action plan with a holistic approach to address adolescent health, such as leveraging communication tools and building collaborations with new and non-traditional partners. CDC's Workgroup on Adolescent, Reproductive and Sexual Health is focusing on different partnerships, research, policies and other components that will be needed to comprehensively address sexual and reproductive health among young persons. CDC is continuing to allocate funds to organizations to build capacity in creating and delivering HIV/STD prevention programs and interventions in schools, correctional facilities, runaway/homeless programs and other settings to reach high-risk youth, young MSM, and young AA and Latino females in various communities.

CHAC applauded CDC's tremendous prevention activities over the past year and its continued efforts to link prevention and care. CHAC particularly commended CDC for taking leadership in the federal government to develop and implement the HNI. The members made a number of comments and suggestions on the future direction of CHAC's advice and recommendations to advance CDC's prevention initiatives.

- CHAC's priority issue over the next two years should be to advise CDC on identifying innovative strategies to reduce new infections in the United States by improving HIV prevention among MSM. HIV testing, implementation of successful interventions in the field and other prevention activities for MSM at the local level have been grossly underfunded for the past ten years.
- CHAC should play a key role in assisting CDC to advance the HNI throughout the country. CHAC members should visit www.healthiestnation.org to join the Healthiest Nation Alliance; encourage their organizations to participate in this important initiative to

improve the overall health of the United States; and include a link to this project on the web sites of their organizations.

- CHAC should provide guidance to CDC on effective approaches to address the prevention and overall health needs of youth as a cross-cutting issue.

Overview of CDC's Revised U.S. HIV Incidence and Prevalence Estimates

Dr. Wolitski explained that the publication of CDC's new HIV incidence estimates in *JAMA* in August 2008 represented a significant advance in the nation's ability to monitor the course of the epidemic. The United States is the first country in the world that created a national system with capacity to monitor new HIV infections in an ongoing manner.

CDC developed two methods to produce the new HIV incidence estimates. The "stratified extrapolation" approach was used to produce national estimates and analyze characteristics of persons who became infected in 2006. This approach is based on surveillance data and both new and standard HIV testing technologies.

The stratified extrapolation approach includes HIV case report data; information collected from local jurisdictions on the testing and treatment history of individuals; and specimens tested with the new BED assay from persons diagnosed with HIV. The BED assay differentiates between recent and long-standing infections and was approved by the Food and Drug Administration in 2005 for surveillance use only.

CDC gathered data from 22 participating sites with name-based HIV reporting that tested >6,800 blood samples. The new HIV incidence estimates were adjusted for reporting delays and redistribution of risk. Estimates for the entire country were produced by using individual estimates from the 22 sites and developing estimates for 70 subgroups based on gender, race/ethnicity, age and transmission risk. These estimates were extended to other states based on the distribution of AIDS cases in those areas.

Results of the stratified extrapolation approach showed that the HIV epidemic is and has been worse than previously known. The rate of new HIV infections was found to be 40% higher in 2006 than prior estimates, but this figure represents a better estimate rather than an actual increase in new HIV infections. Using the stratified extrapolation approach, CDC estimated the number of new HIV infections in the United States to be 56,300 in 2006 with a confidence interval ranging from 48,200-64,500.

By gender, men accounted for 73% and women accounted for 27% of new HIV infections in 2006. By transmission category, MSM accounted for 53%, heterosexual contact accounted for 31%, IDUs accounted for 12%, and MSM-IDUs accounted for 4% of new HIV infections in 2006. By race/ethnicity, AAs accounted for 45%, whites accounted for 35%, Latinos accounted for 17%, Asian/Pacific Islanders (API) accounted for 2%, and American Indians/Alaska Natives (AI/AN) accounted for 1% of new HIV infections in 2006.

The overall rate of new HIV infections was 22.8/100,000 for the entire U.S. population, but the rate among AAs was seven times higher than whites and nearly three times higher than Latinos. The rate of new HIV infections in Latinos was nearly three times higher than whites. By age, the 13-29 age group accounted for 34%, the 30-39 age group accounted for 31%, the 40-49 age group accounted for 25%, and the 50-99 age group accounted for 10% of new HIV infections in 2006. The highest rates of new HIV infections per 100,000 population occurred in the 30-39 and 40-49 age groups.

CDC's "extended back-calculation" approach is a mathematical model that was used to confirm the 2006 estimates produced in the stratified extrapolation approach. This approach included HIV data from 40 states and AIDS data from all 50 states and the District of Columbia. The data were used to estimate trends in HIV incidence from 1977-2006.

Estimates of 55,400 new HIV infections per year from 2003-2006 with the extended back-calculation approach confirmed results of the stratified extrapolation approach. The 95% confidence interval ranged from 50,000-60,000. Trends over time showed that the HIV epidemic has been relatively stable in recent years overall. New HIV infections dramatically increased after 1977, peaked in the mid-1980s, declined with the introduction of HIV testing, further decreased in the early 1990s, slightly increased in 1996 with the introduction of improved ART, and remained relatively stable since that time.

By gender, new HIV infections in males were similar to the overall trend and slightly differed in females. By transmission category, new HIV infections in MSM have steadily increased since the mid-1990s and have continued to decrease in IDUs, heterosexuals and MSM-IDUs since the 1990s. By race/ethnicity, new HIV infections have been stable among whites over the past decade and relatively stable among AAs since the 1990s. Latinos had a small decrease in HIV infections in recent years; API had a dramatic increase in recent decades; and AI/AN had relative stability in recent years.

Data from both the stratified extrapolation and extended back-calculation approaches emphasize that the HIV epidemic is worse than previously known due to increasing HIV infections among MSM and long-standing disparities in the AA and Latino populations. The need for prevention, treatment and medical services has increased because 1.1 million persons are currently living with HIV in the United States.

CDC has achieved success in its prevention activities despite these challenges. HIV incidence and transmissions have been stable overall with significant reductions among IDUs, HIV-positive persons, heterosexuals and mother-to-child transmission. The number of persons with undiagnosed HIV infection decreased from 1 in 4 to 1 in 5. However, individuals, communities and the entire nation need to take additional actions to stop the HIV epidemic in the United States.

CDC supports the call for a comprehensive National HIV Plan for the United States that will encompass HIV prevention, treatment and care. CDC is ready, willing and able to participate in

the development of the National Plan and is currently preparing for this effort. CDC is identifying CHAC members and other national experts to serve on an independent panel to review its HIV prevention portfolio in five areas: planning and monitoring, biomedical and behavioral research, prevention programs and capacity building, surveillance, and policy. The expert panel is expected to complete its review in mid-2009.

CDC is convening the expert panel to enhance transparency and accountability of its prevention activities. The report of the expert panel will be available to the public. The results of the independent review will provide a basis for the development of a new strategic road map for HIV prevention until 2020. CDC expects that the National HIV Plan will establish ambitious goals and measurable objectives to substantially reduce HIV infections and racial/ethnic disparities.

Drs. Fenton and Gerberding provided Congress with an HIV/AIDS “professional judgment” budget and goals for 2015 and 2020 during their testimonies in September 2008. CDC informed Congress that four major goals could be achieved by 2020 with additional resources: reduce the rate of HIV transmission by 50%; reduce the proportion of persons who do not know their status by 50%; and reduce disparities in black-to-white and Latino-to-white ratios of HIV/AIDS diagnoses by 50%.

CDC’s professional judgment budget of \$87 million per year would focus on three major priorities: increase HIV testing and the number of persons reached by HIV prevention programs; develop new tools to fight HIV; and improve systems to monitor and evaluate HIV, related risk behaviors and prevention programs in the field. CDC’s full professional judgment, a video of the hearing and testimony from all witnesses are available at www.oversight.house.gov.

CDC’s current prevention activities are highlighted as follows. Access to HIV testing was significantly expanded with CDC’s allocation of >\$70 million in FY’07-FY’08 for HIV testing to 25 areas with the highest AIDS rates among AAs. Mississippi and Texas were added to the HIV testing initiative in FY’08.

CDC will increase access to HIV prevention by adding 15 new interventions to the Diffusion of Effective Behavioral Interventions (DEBI) Program over the next two years. The new DEBIs will be targeted to AA MSM, STD clinic patients, Latino youth and Latino IDUs. CDC is finalizing the 2008 update of its compendium on the best, most promising or effective interventions.

CDC is developing and evaluating social marketing campaigns and tools. Evaluation results showed that the “Take Charge, Take the Test” campaign increased HIV testing among AA women in two pilot communities. CDC is consulting with communities to develop and target a multimillion dollar campaign to gay and bisexual men with an initial focus on AA men. CDC is conducting research on new behavioral, structural and biomedical interventions to compliment existing interventions in the prevention toolkit.

CDC is increasing community access to its data for prevention planning and also is improving communication of this information. HIV prevalence estimates in the United States were updated and recently published in the *MMWR* in October 2008. A race/ethnicity supplement to the *HIV/*

AIDS Surveillance Report was recently released with new data from Puerto Rico. A report was recently posted on the CDC web site that described patterns of HIV testing among Latinos. A report on HIV incidence in Puerto Rico and the impact of the epidemic in this location will be published in the *MMWR*.

CDC is ensuring that the allocation of resources at national and local levels matches the profile of the epidemic. Supplemental funding of \$4 million was recently awarded to state and local health departments to reassess and strengthen programs for MSM. CDC is increasing its monitoring to assure accountability of prevention activities.

CDC will complete and provide CHAC with the National Monitoring and Evaluation Plan in the near future. The plan will combine indicators from surveillance systems, the Prevention Indicators Project, and the Program Monitoring and Evaluation System to monitor progress in fighting the epidemic at both national and local levels. The plan will describe progress on >30 indicators each year and will be available to the public on the CDC web site.

CDC is continuing to mobilize affected communities and improve collaborations through the Heightened National Response with AA partners, the Latino Executive Committee with Latino partners, and the MSM Executive Committee with MSM partners.

CHAC made a number of comments and suggestions for DHAP to consider in refining its HIV/AIDS prevention portfolio.

- CDC should make stronger efforts to reduce the time in collecting, analyzing and releasing surveillance data. The two-year time lag adversely impacts the HIV prevention-care continuum because HRSA is mandated to allocate Ryan White dollars based on CDC's surveillance data. For example, CDC's most recent HIV incidence and prevalence estimates were published in 2008 based on 2006 data and the surveillance report with 2007 data will be published in 2009.
- CDC should take caution in prioritizing its efforts and funding for MSM. This approach might have an unintended consequence of increasing stigma, characterizing HIV as a "gay disease," or placing other populations at risk. CDC should place equal emphasis on delivering social marketing messages related to sex, HIV testing and prevention to women, heterosexual men and the general public. For example, CDC should widely publicize its comprehensive and broad-based message of the need for HIV testing for any sexually active American 13-65 years of age. This message should be nationally broadcast on radio and television announcements.
- CDC should conduct creative, explorative and innovative research to develop and target interventions to hard-to-reach subgroups. DEBIs are effective because this research is based on volunteers who present for pre-/post-HIV testing. However, DEBI interventions are not designed to reach difficult populations, such as HIV-positive person who knowingly transmit infection.
- CDC should incorporate a mental health component into its HIV prevention activities for MSM.

- CDC should develop estimates of new HIV infections and show trends over time for subgroups within the 13-29 age group.
- CDC and HRSA should ensure that youth are recruited to serve as CHAC members in the future.

Update by the CHAC Ryan White Reauthorization Workgroup

Dr. Sweet announced that the Workgroup held two conference calls in June and October 2008 and agreed on the need to extend Ryan White reauthorization language. Because the current law would sunset on September 30, 2009, the Workgroup extensively discussed three key actions that could be taken to extend Ryan White authorization.

First, the important role of Ryan White should be clearly defined in the healthcare reform plan of the new Administration. Second, Ryan White should be identified as a priority. Third, all parts of the Ryan White appropriation should be improved with clearer language and more resources. This approach would minimize competition among grantees in various parts of the Ryan White legislation.

Dr. Sweet read language into the record that the Workgroup proposed to address these issues.

The current Ryan White Program legislation must be reauthorized or extended as is or with minor changes prior to September 30, 2009 and not get tangled in healthcare reform efforts. Appropriations for the Ryan White Program need to be higher and commiserate with the need for funding. Various constituents and programs must reach agreement on recommended major or minor refinements to reauthorization of the Ryan White Program legislation to ensure that advocates can present a cohesive plan to Capitol Hill rather than making multiple requests with different targets to Congress.

In response to Dr. Sweet's call for a vote, the majority of the CHAC voting members were in favor of a three-year extension of the current Ryan White Program with minimal changes rather than an entire reauthorization of the legislation.

The Workgroup also discussed a number of overarching themes, such as medical and other needs of the aging HIV population; the possibility of using Ryan White dollars for prevention; inclusion of vocational rehabilitation in Ryan White to keep HIV patients in the workforce; a chronic care model for HIV in the AIDS Drug Assistance Program (ADAP) formulary; and the need to identify new champions in Congress for Ryan White.

The Workgroup identified several issues that should be priorities in Ryan White reauthorization: severity of need index (SONI), core medical services, grantee mismanagement, allowance of unobligated funds, Planning Councils, reporting requirements, shortage in the HIV clinical workforce, coordination with other programs, and the Minority AIDS Initiative (MAI).

The Workgroup thoroughly reviewed, considered and discussed language for the extended Ryan White reauthorization proposed by the Federal AIDS Policy Partnership (FAPP). FAPP asked the new Administration to increase FY'09 funding by \$100 million and FY'10 funding by \$614 million in all parts of the Ryan White Program to support the following activities:

- Restore local and state decision-making on funding of transitional housing services for persons with HIV/AIDS by retracting the cumulative 24-month lifetime cap on Ryan White Part A and B coverage of transitional housing established by HAB.
- Conduct a rapid assessment of the state of HIV care and treatment in jurisdictions known to be experiencing administrative difficulties that contribute to poor outcomes for persons with HIV/AIDS (e.g., those individuals in New Orleans and Puerto Rico) within 90 days of the new Administration taking office. Develop a comprehensive corrective action plan that includes immediate and direct federal intervention if necessary to ensure access to the U.S. standard of HIV care and treatment to low-income persons with HIV/AIDS through Ryan White-funded services and other federally-appointed programs, such as Medicaid.
- Revise the ADAP guidance regarding pharmaceutical rebates to ensure that the rebates are not treated as program income. Discontinue the requirement that rebates must be spent prior to the federal grant award.
- Direct HRSA to explore medically prescribed food and nutrition services as a core medical service and evaluate whether clients for whom a nutritional plan is developed through medical nutrition therapy have access to food outlined in the plan.
- Develop a waiver process that provides flexibility to grantees with unobligated funds of more than 2% of their grant awards remaining at the end of the fiscal year to carry over funds due to factors such as large funding increases and shortened timeframes for spending grant dollars.
- Release HIV/AIDS data used to make Ryan White formula allocations in the Part A supplemental scores to ensure that jurisdictions can better predict and prepare for funding shifts.
- Issue guidance affirming the ability of Ryan White Part D grantees to provide continuous services necessary to support optimal health and retain children, youth and families in care through collaboration with other payers to ensure Ryan White remains the payer of last resort for all services, including outpatient ambulatory care and primary medical care.

CHAC extensively discussed the key outcomes of the Workgroup's deliberations, but some members were not in favor of CHAC taking formal action during the meeting. The members noted that pending or unresolved issues in Ryan White reauthorization should be discussed at a future CHAC meeting with the new Administration. Moreover, several CHAC members asked for more details from HAB on FAPP's proposed recommendation to "suspend penalties to grantees for having >2% in unobligated funds."

Dr. Sweet confirmed that CHAC would not take formal action on Ryan White reauthorization at this time because the Workgroup has not completed its charge. However, she noted that

CHAC's consensus on four of FAPP's proposed technical solutions would help to inform the Workgroup's ongoing deliberations:

1. ADAP rebate dollars [CHAC CONSENSUS].
2. Suspension of penalties to grantees for having >5% in unobligated funds [NO CHAC CONSENSUS].
3. Development of memoranda of understanding between Part D grantees and medical care providers to ensure that Part D dollars are not used for medical care and expenses [CHAC CONSENSUS].
4. Distribution of Part A and B resources with the existing formula and supplemental mechanisms through 2012 as well as grants to make SPNS dollars available to cities and states on a continuing basis to support activities to develop, maintain and provide training on the use of the client-level data system [CHAC AGREEMENT TO TABLE UNTIL THE LANGUAGE COULD BE REVIEWED IN WRITING].

Update on HRSA's HIV Workforce Activities

Dr. Laura Cheever, Deputy Director and Chief Medical Officer of HAB, explained that HAB has received anecdotal reports from Ryan White grantees regarding difficulties in hiring and retaining personnel with HIV expertise. To address this concern, HAB developed an internal priority in 2007 to examine issues related to the HIV workforce.

The purpose of this effort is for HAB to determine strategies to support an appropriate workforce to provide high-level, quality and compassionate care currently and in the future through the Ryan White Program. HAB considered this issue in the context of the broader healthcare workforce shortage and decided to initially target the HIV workforce initiative to clinicians.

HAB leveraged FY'08 dollars to conduct two activities. HAB is currently conducting a qualitative study to analyze case studies in five communities and determine workforce shortages in these areas, causes of the shortages, and best practices to address this problem. HAB convened a stakeholder meeting in September 2008 to develop an agenda to make progress on the HIV workforce shortage. The action plan will include programming across HRSA and describe activities stakeholders can conduct at the local level to address the HIV workforce shortage.

The stakeholder meeting was well represented by states, professional organizations, nursing and pharmacy education organizations, workforce and HIV experts, and academic institutions serving AAs and Latinos. The participants examined HRSA's existing resources as well as pathway issues related to pre-professional training and targeting of minority students, other college students, post-graduate students and residents, and professional school students to enter the HIV/AIDS field. The participants also focused on reimbursement and other systems issues that impact the HIV workforce.

HAB highlighted existing challenges in the HIV workforce to provide a context for the meeting. The need for HIV experts to also meet the primary care needs of HIV patients is a challenge. Patient populations have tripled for many grantees over the past ten years, but the level of Ryan White funding has remained the same. The reduction in state Medicaid dollars and other fiscal changes might negatively impact programs and the care of HIV patients. Productivity of the HIV workforce has decreased because clinicians have less time with patients during initial and follow-up visits.

HAB and other HRSA programs are asking providers to conduct more activities in less time. Pre-authorization of drugs that are required by Medicare Part D and other types of insurance is problematic for clinicians. Regional challenges have not been resolved to date. For example, some Part B grantees provide HIV care through state health departments, but the amount of pay for a state health department physician or nurse is capped. The impact of routine testing on the ability of grantees to provide care and treatment to patients is unknown.

Preliminary outcomes of the stakeholder meeting are summarized as follows. The HIV workforce shortage should be addressed in the context of both the primary care and specific HIV needs of patients. HRSA is attempting to identify funds in 2009 to conduct a quantitative study on the workforce shortage. Consideration should be given to changing the current paradigm for HIV care in which primary care and specialized HIV care would be separated and provided at two different clinical sites. Some stakeholders did not agree with this suggestion.

Incentives should be offered to physicians and nurses who enter the HIV care field, such as more exposure in residency and nursing school programs and medical school. Strategies should be explored to overcome policy issues or statutory language that might serve as a barrier to engaging the National Health Service Corps in this effort. The possibility of using "medical home" legislation to address the HIV workforce shortage should be considered. Productivity standards should be established for personnel who provide HIV care.

The report of the stakeholder meeting will be widely distributed and posted on the HAB web site. HAB will compile feedback from the meeting to develop an internal work plan of its activities over the next 12 months. HAB will continue to extensively involve stakeholders in the HIV workforce initiative.

CHAC thanked HAB for convening the stakeholder meeting to address the important and complex issue of the HIV workforce shortage. The members made three key comments for HAB to consider in further developing and launching this initiative.

- HAB should lead a partnership effort with states and Eligible Metropolitan Areas (EMAs) to gather baseline data for the workforce shortage quantitative study.
- HAB should engage in discussions with the Accreditation Council for Graduate Medical Education and the American Board of Internal Medicine to explore the possibility of requiring residents to have HIV outpatient experiences.
- HAB should ensure that its HIV workforce initiative also includes clinicians who provide HIV treatment and care in correctional settings.

Update on HAB Quality Measures

Dr. Cheever reported that all Ryan White grantees are required to establish clinical quality management programs, including the development and use of performance measures. In the “Measuring What Matters” report that was published in 2003, the Institute of Medicine (IOM) acknowledged HAB’s previous quality activities and recommended the development of quality measures for Ryan White grantees.

In response to the IOM report, HAB created a quality road map and convened an internal workgroup in 2005 to identify potential indicators. HAB used the IOM recommendations as a guide in developing the quality measures and considered the size of the impacted population, the evidence base to support a particular practice, and the degree to which the measures could achieve improvements. HAB solicited public comment prior to finalizing the measures.

HAB released 28 measures in three groups in 2007 for clinical HIV care of adults and adolescents. HAB awarded a contract to the National Committee for Quality Assurance in 2007-2008 to convene a stakeholder group to ensure that its performance measures were aligned with existing national measures. However, the HAB measures were not fully aligned with other national measures due to specific expectations and requirements of the Ryan White legislation.

The HAB performance measures are aligned with HRSA Office of Performance Review measures, HRSA-wide core measures, the HAB client-level data reporting system, and the HAB HIVQUAL-US Continuous Quality Program. The HAB measures also were included in HRSA’s electronic CAREWare health information system. The ADAP, case management, dental services and systems level measures were developed in 2008 for states and EMAs and will be available for public comment until December 15, 2008.

Ryan White grantees are encouraged to include core clinical performance measures in their quality management plans, but are not required to use the measures or submit performance measurement data to HAB. HAB developed a *Companion Guide* to answer frequently asked questions (FAQs) and posted the document on its web site. The FAQs are updated as new measures are released.

The “Group 1” clinical performance measures have a significant impact on mortality or transmission and are deemed to be critical for HIV programs to monitor. The five Group 1 measures include ART for pregnant women, CD4 T-cell count monitoring at least twice per year, use of highly active ART (HAART) in AIDS patients, medical visits at least twice per year, and prescriptions of pneumocystis carinii pneumonia prophylaxis for patients with CD4 counts <200. The Group 1 measures were finalized based on public comments and in-depth interviews with grantees and posted on the HAB web site in December 2007.

The “Group 2” clinical performance measures reflect important aspects of care that impact HIV-related morbidity and affect a sizeable population. The nine Group 2 measures include adherence assessment and counseling; HBV vaccination; HIV risk counseling; oral examination; and cervical cancer, HCV, lipid, syphilis and TB screening. The Group 2 measures were finalized and posted on the HAB web site in the summer of 2008.

The “Group 3” clinical performance measures reflect important aspects of care that impact HIV-related morbidity and affect a sizeable population. Some of the Group 3 measures duplicate Group 2 measures, might be difficult to measure, or may have no scientific data to recommend a certain practice. HAB expects to delete some of these measures based on public comments submitted.

The 13 Group 3 measures include Mycobacterium avium complex prophylaxis; hepatitis A, influenza and pneumococcal vaccination; smoking cessation; alcohol counseling; basic patient education; and chlamydia, substance abuse, mental health, gonorrhea, HBV and toxoplasma screening. The Group 3 measures will be finalized and posted on the HAB web site in early 2009.

HAB drafted service category measures in four areas to expand the range of performance measures that are available for use by Ryan White grantees. Many of the measures were developed and tested through quality management initiatives supported by HAB. Draft measures in the ADAP category include application determination, eligibility re-certification, and inappropriate antiretroviral regimens or components reviewed and resolved by ADAP.

Draft measures in the oral health category include dental health history and a treatment plan, oral health education, periodontal examination, and completion of a Phase 1 dental treatment program. Draft measures in the medical case management category include a care plan for each patient that should be reviewed every six months and at least two medical visits.

Draft measures in the system-level category include disease status at time of entry into care, test results for HIV/AIDS-positive persons, existence of a quality management program, the time lag for initial access to ambulatory primary care, and the achievement rate of selected HAB HIV performance measures. HAB will review all of the performance measures on an annual basis and make changes as needed.

HAB developed and released detail sheets with each performance measure to provide more information on the measure, including the numerator/denominator; patient exclusions; data elements and sources; national goals, targets and benchmarks; outcome measures for consideration; basis for selection and placement in the measurement group; *U.S. Public Health Service Guidelines*; and references and notes.

CHAC commended HAB on its tremendous effort to introduce a culture of quality improvement to HIV/AIDS care and treatment. Several CHAC members made comments and suggestions for HAB to consider in revising the HIV performance measures in the future.

- Ryan White grantees should be “required” rather than “encouraged” to implement the Group 1 measures as the standard of care for HIV/AIDS patients.
- “Viral load” should be added as a new Group 1 measure because this test informs clinicians of drug resistance or medication adherence of their patients. CD4 counts would not significantly change in three months to provide clinicians with this information.
- “Rectal cancer screening” should be added as a new Group 2 measure.
- “Substance abuse screening and counseling” should be a revised Group 3 measure.
- Mental health screening as a Group 3 measure will be problematic. Patients typically submit inaccurate self-reports on mental health issues. Staff with minimal training or non-experts generally conduct mental health screening. Mental health and psychosocial assessments should be equivalent to screening measures for the medical component.

With no further discussion or business brought before CHAC, Dr. Sweet recessed the meeting at 4:50 p.m. on November 17, 2008.

Panel Presentation on the Mental Health Services-HIV/STD Interface

Dr. Sweet reconvened the CHAC meeting at 8:32 a.m. on November 18, 2008 and yielded the floor to the first presenter.

Dr. Deborah Parham Hopson, Administrator of HAB, moderated a panel presentation on the mental health services-HIV/STD interface, including comprehensive and synergistic care as well as risk issues. Overviews by four HHS agencies are summarized below.

Substance Abuse and Mental Health Service Administration (SAMHSA). Ms. Ilze Ruditis is an HIV Program Officer in the SAMHSA Center for Mental Health Services (CMHS). She joined the CHAC meeting by conference call and explained that the CMHS Mental Health-HIV Program provides integrated and linked comprehensive care to a population with multiple risks. Other SAMHSA centers serve the same population and use CDC’s DEBI Program to provide HIV prevention services in the context of substance abuse prevention and treatment. These HIV prevention efforts directly support STD prevention and assure access to STD treatment.

Factors that elevate the risk for HIV infection in psychiatric consumers include sexual behavior, alcohol or other drug abuse, and poverty, homelessness or other environmental factors. Studies in the 1990s estimated that the rate of HIV infection among persons with serious mental illness was 10% or 25 times higher than the general population. A more recent multi-site study estimated that HIV rates among mental health consumers ranged from 2%-5% in rural and metropolitan areas. A 2007 study showed that the HIV rate among persons with serious mental illness was much higher than the estimated prevalence of 0.6% in the general population.

Key milestones from CMHS’s HIV/AIDS history are highlighted as follows. CMHS’s five-year demonstration project in 1992-1997 with 11 sites led to the development of *Mental Health Care for People With or Affected by HIV/AIDS: A Practical Guide*. CMHS led the “HIV Treatment

Adherence, Health Outcomes and Cost Study” in collaboration with federal partners. CMHS used MAI funding allocated by HHS to create the Mental Health HIV Services Collaborative (MHHSC) Program in 2001. The number of MHHSC grantees decreased from 20 in the 2001-2005 cycle to 16 in the current 2006-2010 cycle.

The mission of MHHSC is to expand local capacity to provide accessible and culturally competent HIV/AIDS-related mental health treatment and case management services to minority communities. MHHSC’s target population includes HIV-positive persons who have mental health problems with or without a formal diagnosis and family members or significant others included in the individual treatment plan of the primary client. Of MHHSC clients, 74% are 35-54 years of age, 64% are male and >70% are AAs.

MHHSC’s total annual budget is \$8.4 million and each grantee is awarded up to \$525,000 per year for five years. MHHSC grantees provide services in 30 settings and include CHCs, community mental health centers, substance abuse treatment programs, academic health centers and AIDS Service Organizations. MHHSC grantees have served 2,300 persons in the current five-year cycle to date.

MHHSC grantees provide a range of services to primary clients and their family members or significant others: mental health assessment; treatment and support services in both traditional and non-traditional settings; case management and psychiatry services; individual treatment plans; establishment and maintenance of Consumer Advisory Boards; community linkages to assure primary and specialty care, substance abuse treatment and HIV testing; and HIV rapid testing.

CMHS evaluates each individual MHHSC site and also performs a cross-site assessment. Three professional associations were awarded funding to offer online training and education to HIV mental healthcare providers at low or no cost. Since 1996, the professional associations have had >30,000 face-to-face training contacts with front-line mental healthcare providers.

CDC. Dr. Marc Safran is a board-certified psychiatrist, a captain in the U.S. Public Health Service, a member of CDC’s Division of STD Prevention, and the founding chair of CDC’s Mental Health Workgroup. He explained that CDC formed that agency-wide workgroup in 2000 to promote collaboration and advancement in the field of mental health in support of its mission. The work group grew to include >100 members. Dr. Safran also leads NCHHSTP efforts related to “mental health and infectious disease.” His presentation today was entitled “HIV, STDs, and Mental Health.”

Dr. Safran noted that CDC has recognized the need to integrate attention to mental health into HIV/AIDS services for quite some time. CDC’s National AIDS Hotline was the largest public health hotline in the world in 1994 and fielded ~1.5 million calls each year. At the time, Dr. Safran found a significant proportion of the hotline’s calls to be related to mental health issues, and that hotline staff received no training in how to respond to such calls. The hotline staff was subsequently trained about mental health issues that arise in the context of providing HIV/AIDS information, and about potential strategies for providing such information and mental health

referrals in the context of mental-health related calls. CDC published some of Dr. Safran's findings regarding mental health-related calls to the hotline in *AIDS Education and Prevention* in 1996.

Dr. Safran stressed that CDC has continued to use the Surgeon General's 1999 report on mental health to emphasize the importance of integrating mental health and HIV/AIDS services. The report estimated that 1 in 5 Americans have "mental disorders" defined as health conditions characterized by alterations in thinking, mood or behavior and associated with distress or impaired functioning. The report also defined "mental health" as successful performance of mental functions in terms of thought, mood and behavior that results in productive abilities, fulfilling relationships and the ability to adapt and cope. The report concluded that most persons with mental illness do not seek treatment.

Dr. Safran shared the story of the tragic death of a colleague's brother about a year ago. It was the story of a life cut short by failure to prevent and diagnose HIV in a man whom no one had ever thought to ask about HIV risk behavior or to test for HIV even as his unexplained medical symptoms grew more and more severe over several months. Because this man's mental status had always been somewhat impaired by what was probably a developmental disorder that had never been fully evaluated nor precisely diagnosed, and because he lived with a respected family that always cared for him since his birth in the 1960s, no one ever thought he might have ever been exposed to any type of activities that could have put him at risk for HIV,...until a positive test a couple of weeks before he died.

Dr. Safran stated that mental health can substantially impact HIV and STD related risks, needs, and services - and can be impacted by them as well - but that neither mental health nor HIV/STD prevention receive adequate attention in our society. He stated that this is very relevant to CDC and HRSA as Federal agencies involved in HIV/STD prevention. He recommends that CDC, HRSA, and their public health partners do more to address this issue.

National Institutes of Health (NIH). Dr. Christopher Gordon is Chief of the Secondary HIV Prevention and Translational Research Branch at the NIH National Institute of Mental Health (NIMH). He explained that the NIMH Center for Mental Health Research on AIDS conducts activities in four major areas: basic and clinical neuroAIDS, HIV primary prevention, HIV secondary prevention and translation, and cross-cutting HIV programs.

Programs in NIMH's integrated HIV research portfolio on the mental health of AIDS are highlighted as follows. The "Neuropsychiatry of HIV/AIDS Program" supports evaluation of HIV-associated neurological and neuropsychiatric complications and assessment of the impact of the HIV epidemic on persons with serious mental illness. These research projects focus on access to treatment and mental health services for HIV-positive persons and are designed to better understand risk behavior patterns in this population.

The "Secondary HIV Prevention Program" supports studies to reduce transmission behaviors among HIV-positive persons and understand factors that influence risk behaviors. NIMH released an FOA to support the development of interventions to reduce HIV transmission

behaviors and disclose HIV serostatus and also to facilitate research to address stigma, discrimination and intimate partner violence among HIV/AIDS-positive persons. Mental health considerations, international settings and developmental considerations will be key focus areas of this extramural research project.

Grantees will be encouraged to consider a number of mental health issues in conducting their research projects. The best intervention data are available for persons with a history of trauma or current depression, but no interventions have been developed to date to prevent the onset of mental disorders among HIV/AIDS-positive persons.

Constructs of interest other than mental disorders should be addressed, such as HIV/AIDS patients who are difficult to manage due to certain personality traits. Additional research is needed to determine the mechanisms of risk behavior or treatment adherence problems. More efforts are needed to compile and disseminate effective interventions. Emphasis should be placed on both mental disorders and risk adherence in an integrated manner.

NIMH convened a meeting in July 2007 with researchers, clinicians, consumers and other leaders in the field to identify and discuss current gaps in mental illness and HIV regarding prevention, diagnosis and treatment. The meeting report will soon be published in *AIDS and Behaviors* and will provide important guidance to the field.

The “Adherence Program” supports the development of novel interventions with sustained impact and outcomes beyond adherence to a daily ART regimen, such as linkages to care, retention in care, and readiness and initiation of ART when indicated. The program also supports research in international settings and underserved groups, formative research on structural factors, studies on intersections between adherence and prevention, and translational research in the adherence domain.

NIMH and the International Association of Physicians in AIDS Care will sponsor the 4th International Conference on HIV Treatment Adherence on April 5-7, 2008 in Miami, Florida. The overarching purpose of the conference will be for researchers and clinicians to develop hands-on tools to disseminate treatment adherence interventions. The deadline to submit abstracts in December 1, 2008. NIMH released an FOA to identify gaps and priorities in disseminating HIV prevention and treatment adherence interventions. This research will focus on dissemination strategies and the adoption, effectiveness and sustainability of interventions.

A 2008 published study highlighted the success of NIMH’s extramural research on interventions that reduced risk behaviors in persons with a history of childhood sexual abuse. A significant reduction was observed in unprotected vaginal or anal sex in the sample of the cohort that was randomized to the coping group compared to the support group. Of the entire cohort, ~85% was minority and ~60% reported sex with men. The study will be reported in CDC’s updated compendium of successful interventions.

A study that is in press analyzed the use of cognitive behavioral therapy for adherence and depression. The study found that 12 sessions of therapy linking depression and adherence behaviors produced a significant effect with Medication Event Monitoring System outcomes.

HRSA. Dr. Kaytura Felix is the Chief Medical Officer in the HRSA Bureau of Primary Health Care. She explained that Federally Qualified Health Centers (FQHCs) provided services to 16.1 million patients in 2007 or 1 in 20 Americans. Of these patients, 91% were below 200% of the federal poverty level; 39% were uninsured; 930,589 were homeless; 826,977 were migrant or seasonal farm workers; and 133,518 were public housing residents.

Medicaid and HRSA grants are the two largest funding sources for FQHCs and collectively account for 54% of revenues. The FQHC workforce of >100,000 staff, including 12,700 physicians, nurse practitioners, physician assistants and midwives, managed 63 million patient visits in 1977 at >7,000 service sites. FQHCs have provided primary care for the past 40 years.

FQHCs are located in or serve high-need communities. Of all FQHCs, 52.8% are in rural areas. FQHCs are governed by Community Boards to provide comprehensive primary health care services and education, translation, transportation or other supportive services. Services are available to all persons and fees are adjusted based on ability to pay. FQHCs meet performance and accountability requirements and are required to report on Pap testing, hypertension and diabetes control, immunization in children, and mental health and behavioral measures.

FQHCs are currently facing a number of critical workforce issues in providing primary care to patients. The reimbursement structure is problematic because counseling and other patient communications are not reimbursed. The excessive amount of administrative requirements has decreased the number of medical school students who choose primary care as a specialty.

Salaries of new primary care physicians are not commiserate with the debt accumulated in medical school. Retirements in the aging workforce have led to gaps in expertise in the field. Primary care providers are required to have knowledge in several areas to meet the full health needs of their patients. A recent study showed that 17.4 hours are needed for primary care providers to offer all preventive care and chronic care services for their patients.

A medical home has been proposed as the national response to primary care workforce issues. A "medical home" is defined as primary care that is accessible, continuous, comprehensive, family-centered, coordinated, compassionate and culturally effective. The characteristics of a medical home include a personal physician, provider-directed medical practice, whole-person orientation, coordinated or integrated care, quality and safety as hallmarks, availability of enhanced access to care, and payment to appropriately recognize added value.

A 2001 published study showed that 51% of low-income patients in one setting had at least one psychiatric diagnosis compared to 28% of the general population. Of all patients included in the study, 90% preferred integrated primary care and mental health services in one setting. Of all mental health patients, 56% receive services in primary care settings.

HRSA awards expansion grants for FQHCs to provide mental health/substance abuse (MH/SA) services onsite or at an offsite location through a contract. HRSA awarded 184 expansion grants totaling \$23.5 million in 2002-2008. Of all FQHCs, >76% provide MH services onsite, >51% provide SA service onsite, 91% provide HIV testing and counseling, and 164 provide early intervention services with Ryan White Part C dollars.

FQHCs with expansion grants are expected to develop and maintain a high level of service that includes licensed MH/SA staff; effective risk management practices; incorporation of program activities into the FQHC quality plan; provision of access to expanded MH/SA services within 120 days of award; and clearly defined healthcare plan goals and objectives to improve the health outcomes of patients, enhance management of MH/SA disorders and apply exemplary practices and lessons learned.

FQHCs use several models to integrate mental health into primary care, such as preferred referrals, co-location and integration. The role of behavioral health consultants in primary care is to manage the psychosocial aspects of chronic and acute diseases and apply behavioral principles to address lifestyle and health risk issues. Behavioral health consultants emphasize prevention and self-help approaches; partner with patients in a treatment approach that builds resilience; encourage personal responsibility for health; and provide consultation and co-management services in the treatment of mental disorders and psychosocial issues.

CHAC thanked the panelists for describing the integrated mental health-HIV/STD activities of their respective agencies. CHAC used the discussion period as a question/answer session with the panelists. Because this complex issue was presented to CHAC for the first time, several members were in favor of exploring strategies at a future meeting for CHAC to address the mental health-HIV/STD interface in a formal process.

Overview of the Bureau of Primary Health Care (BPHC)

Dr. Felix explained that BPHC's mission is to improve the health of the nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent and quality primary healthcare services. BPHC has expanded access to FQHCs with an increase in the federal appropriation from ~\$1.3 billion in 2002 to ~\$2 billion in 2007 and an increase in the number of grantees from 848 in 2002 to 1,076 in 2007.

In terms of HIV care, 33% of CHCs are Part C grantees and 10% receive Part C funding. HIV services are available at both Ryan White-funded and non-funded sites. Based on 2007 data, CHCs served 61,000 patients with symptomatic HIV, 25,000 patients with asymptomatic HIV, and 670 HIV-positive pregnant patients. CHCs performed HIV testing on 504,000 patients. In terms of counseling and testing, 91% of CHCs provide these services on site, 12% provide these services by referral/grantee payment, 45% provide these services by referral/grantee non-payment, and 99% provide these services by one or more delivery method.

BPHC and CDC collaborate under a cooperative agreement to improve prevention and care in CHCs. Previous interagency activities have included (1) an environmental scan to assess HIV care in CHCs; (2) a National Survey Education Campaign that informed the development and dissemination of an operational guide, policy recommendations, communications and training on routine HIV screening in primary care settings; (3) effective models to increase access to HIV screening services; (4) strategies to link HIV-positive persons to appropriate IV primary care; and (4) promotion of HIV testing in CHCs.

BPHC, CDC and the National Association of Community Health Centers jointly developed a report on routinizing HIV testing in CHCs. The report outlined a number of guiding principles for CHCs to consider in this effort. HIV is a chronic illness. The patient is the unit of analysis. Routine testing should be provided on the same day across the organization. Change theories, redesign and collaborative learning models, and lessons learned should be applied.

The CHC should use its existing infrastructure and assets to routinize HIV testing. Community and state partnerships should be leveraged. Momentum, trust, support and quality outcomes with intense coaching should be created. The chronic care model with self-management support, delivery system design, decision support and clinical information systems should be incorporated into CHCs to improve outcomes.

Several lessons have been learned over the past ten years in applying redesigned principles for diabetes and other disease models to provide optimal care to patients, such as not moving the patient, increasing clinician support, creating broad work rules, organizing care teams, communicating directly and starting all visits on time. To routinize HIV testing and share other responsibilities for patients, CHCs have implemented the patient flow model by engaging the front desk, waiting room, vital area, examination room, laboratory, checkout area and all other components of their organizations. In addition to implementing the patient flow model, CHCs also are routinizing testing with an HIV screening algorithm

BPHC took several actions to routinize HIV testing in CHCs. Needs assessments were conducted and endorsement was obtained from CHC leadership. CHCs, infectious disease specialists and other community resources built external partnerships. The current HIV screening model was evaluated. A data collection system and tool were developed to track information. Referral arrangements were established and strengthened.

An all-staff workshop and educational forum were held. Staff was trained in administering the rapid HIV test and a data collection process was launched. Routine HIV screening and data collection were implemented as organization-wide activities. Efforts were made to sustain routine HIV testing in CHCs through periodic site visits, ongoing support, intensive coaching, linkages to local and state training support, and review, feedback and correction of data.

CHCs currently use the following HIV testing model. A nurse offers HIV screening during intake and obtains a sample from the patient at that time. Routine HIV testing is offered to all patients 13-64 years of age, but patients can refuse testing. HIV testing data are collected based on the

acceptance or refusal of patients. Providers submit all reactive and non-reactive results to HRSA. Confirmatory testing is performed at the time of the visit for all reactive results.

BPHC piloted routine HIV screening in a rural CHC at four sites that served 15,000 patients and had 29,000 encounters. Key results of the pilot project are highlighted as follows. Of the total patient population, 99% were AA and 46% were uninsured. The distance between the rural CHC and the closest Ryan White Program was 24 miles. The patient flow model was used to provide routine HIV testing to patients. The rural CHC provided 135 HIV tests to non-pregnant patients and 141 HIV tests to pregnant patients.

Of 2,992 patients who were offered HIV testing, 83% accepted and 17% refused. The acceptance rate was 67% among females and 61% among males. Of 2,496 patients who accepted the test, 58% had never been tested for HIV in the past, 12% previously had ≥ 3 HIV tests, 16 were reactive and 8 were reactive with a positive Western blot. Of 496 patients who refused the test, 44% believed they were not at risk.

The pilot project in the rural CHC was successful in a number of areas, including simultaneous rollout of routine HIV screening at all clinic sites, an extremely high acceptance rate of rapid HIV testing among patients, the ability of a key cohort of staff to offer rapid HIV tests to the majority of patients, full staff participation in and endorsement of routine HIV screening, the provision of important education to staff, and partnerships to retain patients in care.

BPHC also piloted routine HIV testing in six CHCs at 19 clinical sites in three Southeastern states. Implementation of routine HIV screening required <3 months per site. Of all patients involved in the three-state pilot, ~18,000 accepted rapid HIV testing as part of their routine primary care visit.

Of all patients who refused testing, 69% believed they were at low risk, 26% were recently tested, and 10% postponed the test for another time. The CHCs learned that walk-ins were less likely to accept testing. AAs, whites and uninsured patients were offered testing more often than other groups. The majority of patients who accepted testing were <55 years of age, women, AAs and Latinos.

Perspectives from patients, providers and communities regarding routine HIV testing in CHCs focused on the convenience of being tested during the primary care visit; the need for CHCs to develop a concrete plan to address false-positive results and decrease the time between testing and retesting; and the need for CHCs to increase efforts to reach HIV-positive patients.

Key findings of the three-state pilot are highlighted as follows. "Routine" HIV screening in CHCs does not include "every" patient and might only include 33% of the patient population. The three-state pilot resulted in confirming 17 new HIV infections. The rationale for differences in routine HIV screening should be determined, such as patients who accept testing versus those who refuse and the variability in the rate of offering tests across CHCs.

Latinos were less likely to be offered testing, but were more likely to accept testing. Training and the lack of translation or interpretation services might serve as barriers to more universal access to testing for Latinos. Innovative strategies might be needed to increase testing for men. A new algorithm, such as two rapid tests, might be needed to address false-positive results in low prevalence settings. Implementation of HIV screening in CHCs was found to be feasible and acceptable to patients and providers, but cost was an issue that needs to be addressed.

Systems should be designed to meet the needs of patients. The current CHC infrastructure should be reformed to reduce barriers. Prevalence rates should be addressed and patients should be retained in care. Corrections and behavioral health should be incorporated into HIV care. BPHC will continue to partner with CDC to gather data on patient perceptions and attitudes regarding routine testing; expand the routine HIV testing pilot to include ten additional CHCs; incorporate virtual collaborative techniques to broaden the reach of routine HIV testing for CHCs; and explore strategies to implement rapid HIV testing in dental clinics.

CHAC thanked Dr. Felix for presenting a comprehensive overview of BPHC. Several members emphasized the need to place regular updates by BPHC on future CHAC agendas because CHCs serve as a vital linkage to HIV testing and care in the country. CHAC made a number of comments and suggestions for BPHC to consider in refining its primary care activities.

- The CHC model of “offering” HIV testing is contrary to “routinizing” testing because patients are allowed to opt-out.
- BPHC has not leveraged new funds for CHCs to routinize testing or provide treatment and care to patients who are found to be HIV-positive as a result of routine testing in CHCs. CHCs do not have sufficient capacity, funding or other resources at this time to routinize HIV testing or provide treatment and care to potentially several thousands of new HIV-positive patients who will be identified each year.
- BPHC should take caution in estimating HIV prevalence in CHCs because only ~33% of patients were tested in these settings.
- BPHC should take aggressive actions to ensure that CHCs offer the same level of testing to Latinos as other groups. Many CHCs have large Latino patient populations and should currently have translation/interpretation services available to offer routine HIV testing.
- BPHC should not expand the routine HIV testing pilot to include ten additional CHCs. Instead, BPHC should compile and distribute existing data from the pilot and direct all FQHCs, federally-funded community-based organizations and other sub-grantees to routinize HIV testing at all sites.
- BPHC should collect data on the number of patients who receive rapid HIV testing and do not present for the confirmatory test at a later time. These data might assist BPHC in making a strong case on the need for funding to support rapid confirmatory HIV testing.
- BPHC should take caution in including HIV in the chronic care model. HIV is a public health issue and the chronic care model does not address prevention in HIV-positive persons.

Panel Presentation on ART Resistance in International Settings

A panel of CDC and NIH staff described programmatic activities and research projects that are being conducted to better understand and monitor ART resistance in international settings. Overviews by the two HHS agencies are summarized below.

NIH. Dr. Jeffrey Nadler is the Acting Director of the Therapeutics Research Program (TRP) at the NIH National Institute of Allergy and Infectious Diseases. He explained that the primary principles of ART resistance include baseline genotype to allow clinicians to select better ART for both treatment-naïve and treatment-experienced patients. More active drugs translate to better long-term responses, less accumulation of additional resistance and preservation of drugs.

TRP prioritized the international view of therapeutics research with a focus on testing and virologic confirmation of treatment failure as well as baseline testing to avoid failure, obtain an individual benefit, and conduct population sampling to evaluate study results and inform recommendations.

Resistance testing methods include population sequencing for transmitted resistance, site-level resistance assessment to make localized recommendations and resistance during therapy. In the traditional approach, resistance is measured from plasma. However, this approach raises issues in many countries related to costs for equipment, training, reagents and specimen transport.

To address these issues, TRP is currently exploring newer technologies to apply in research in developing countries. These technologies include dried blood spot to eliminate plasma, new transport systems, and cost-effective methods to obtain, store, transport and assess specimens. LiqAmp and other sequence-focused technologies identify specific mutations in a sequence and eliminate the need to perform a full sequence. Minority species sampling is another resistance testing method that might have implications for practice, but this technology has limited availability internationally.

WHO has a global surveillance focus and is attempting to perform systematic data collection and sampling from a much larger data set. WHO established thresholds of up to 5% and 5%-15% for baseline and community resistance. TRP has an advisory role in the WHO program. In terms of PEPFAR, the primary focus is on resistance during therapy. However, restrictions are due to limited laboratory resources and a threshold for testing has not been established to date.

The limited availability of agents might reduce the imperative for testing of naïve patients in international settings, particularly when combined with resource limitations. TRP, CDC, WHO and PEPFAR are current making efforts to create a catalog of contributing conditions for the development of resistance, such as stock-outs and patients lost to follow-up.

Dr. Heather Watts, from the NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development, described NIH's research projects focusing on ART resistance in the prevention of MTCT (PMTCT) in international settings. NIH funded individual research grants, clinical trials and cohort studies in pregnant and postpartum HIV-infected women and infants who became infected despite prophylaxis in international settings. These studies focused on the prevalence, incidence, risk factors, pathogenesis and prevention of ART resistance and the effect on response to subsequent therapy.

Data were collected from an NIH-funded cohort study in Latin America and published in 2008. The study showed that of 197 pregnant women who received HAART for prophylaxis, 18% had ART drug-resistant mutations. Secondary analyses of NIH-sponsored clinical trials were used to define the problem of the development of resistance in PMTCT. The HIVNET 012 trial was the first study to define the problem of nevirapine (NVP) resistance in women and infants who became infected despite prophylaxis. Secondary analyses of clinical trials in Thailand and Botswana evaluated NVP resistance in women exposed to single-dose NVP in the context of short-course azidothymidine (AZT).

Secondary analyses of NIH-sponsored clinical trials and primary investigator-initiated studies were conducted to determine risk factors for drug resistance, including the role of low CD4 count/high viral load, viral subtype and prolonged half-life of NVP. Secondary analyses also were conducted to determine ART drug resistance in infected infants. The analyses showed that NVP resistance in infants was independent of maternal resistance and receipt of AZT in infants or the lack of maternal intrapartum NVP doses significantly reduced the risk of NVP resistance in infants. The analyses also analyzed the dynamics of fading resistance over time.

Samples from pathogenesis-based research on ART drug resistance in PMTCT were used to support investigator-initiated studies. This research focused on the development of sensitive assays to detect minority quasi-species and facilitate easier use of these tests around the world. Trials in Thailand, Botswana and South Africa on responses to therapy and ART resistance in PMTCT in women showed no difference in CD4 response in any of the cohorts.

In the Thailand trial, 38% of women had CD4 counts <50 six months post-HAART with NVP resistance at ten days versus 68% of women who had CD4 counts <50 without NVP resistance. In the Botswana trial, higher viral failure was observed when HAART was started <6 months after single-dose NVP, but a similar response was seen when therapy was started >6 months after single-dose NVP. Follow-up of the Botswana cohort is being continued. In the South Africa trial, no difference was observed in HIV RNA response. A clinical trial is underway to link studies in women regarding responses to NVP versus a lopinavir or ritonavir regimen with or without prior single-dose NVP.

Trials in Thailand and Uganda focused on responses to therapy and ART resistance in PMTCT in infants. In the Thailand trial, the median age of infants who were started on HAART was eight months. Higher viral failure was observed if the infant became infected despite single-dose NVP. In the Uganda trial, the median age of infants who were exposed to single-dose NVP was 1.7 years. No difference in response was observed between infected infants who

were and were not given single-dose NVP. To determine an optimal regimen, NIH is funding three ongoing clinical trials to assess infant response to therapy after infection despite single-dose NVP.

To reduce the development of resistance after single-dose NVP, NIH is funding two clinical trials to evaluate the optimal “tail” regimen and duration of regimen. Various regimens of 7 days or 7-30 days are being used in the trials to prevent ART resistance in PMTCT. In its ongoing research on ART prophylaxis of breastfeeding transmission and resistance, NIH recognizes that avoidance of breastfeeding for HIV-infected women is not safe or desirable in most parts of the world.

Trials in Ethiopia, India, Malawi and Uganda showed that reduction in HIV transmission is possible by administering NVP prophylaxis to infants during breastfeeding and HAART to mothers during breastfeeding. The trials demonstrated a significantly higher risk of NVP resistance at 6 weeks if infants received extended NVP. No difference was observed in infants who no longer received NVP and were infected after 6 weeks.

NIH’s PROMISE study is a large trial that is currently undergoing review to define an optimal regimen for PCMTC for mothers with CD4 counts >350 who do not need treatment for their individual health. In the antepartum randomization, maternal HAART will be compared to short-course AZT plus single-dose NVP with a seven-day tail of tenofovir disoproxil fumarate/emtricitabine to prevent resistance. In the postpartum randomization, maternal HAART will be compared to infant NVP throughout the duration of breastfeeding.

CDC. Dr. Elliott Raizes, of the GAP Care and Treatment Branch at CDC, explained that PEPFAR-supported countries need directed surveillance activities to inform programs, improve patient outcomes, and prevent emergence and transmission of HIV drug resistance (HIVDR). Since 2003, PEPFAR and other donors have contributed to the rapid scale-up of ART in resource-limited settings and are now providing ART to >3 million HIV/AIDS-positive persons in these areas.

As of March 2008, ART was being provided to >1.6 million persons in the 15 PEPFAR focus countries. A 2006 published study showed that rates of virologic suppression and adherence in these countries were similar to resource-rich settings. The ART strategy is implemented based on WHO guidelines: two NRTIs and 1 NNRTI for first-line drugs, two NRTIs and protease inhibitors for second-line drugs, and limited clinical and biological monitoring.

HIVDR surveillance is a high priority in PEPFAR. Under the WHO/HIVResNet collaboration, a strategy was developed for prevention of HIVDR. PEPFAR is making advancements through collaborations with CDC, NIH and other agencies to develop and implement PEPFAR- and WHO-specific strategies.

Efforts are underway in PEPFAR to address a number of outstanding concerns related to the emergence of HIVDR, including impacts from the lack of virologic monitoring, effects of single-dose NVP exposure, use of AZT or stavudine-containing regimens instead of tenofovir, use of

NNRTIs instead of protease inhibitors in all first-line regimens, lack of efficacy data on the effectiveness of second-line regimens in resource-limited settings, effects of ART programs on transmission of resistance, and the prevalence of baseline mutations at the start of ART.

Recent data showed that a resistance pattern in Malawi indicated a compromised response with second-line therapy. NIH issued a press release announcing that single-dose NVP compromised the use of NNRTIs in women. A study in Zambia showed that baseline NNRTI resistance was higher than expected in a reportedly naïve population.

The WHO strategy for HIVDR surveillance includes a focus on ART program evaluation with some laboratory components and surveillance of HIVDR across site risk factors to detect HIVDR emergence, HIV patients receiving first-line ART, and individuals recently infected with HIV. The objective of the WHO HIVDR surveillance and monitoring strategy is to support ART program practices that assess and prevent HIVDR emergence and transmission. HIVDR Task Forces are established in countries to implement the WHO strategy and guide the drug-resistant component of national ART programs.

The WHO strategy includes three levels of assessment. Level 1 is an early warning indicator (EWI) assessment at facility and national levels to assess the ability of ART programs to optimize prevention of HIVDR. EWIs are monitored annually, reported on a site basis, extracted from existing medical records and pharmacy systems, and monitored in all or representative ART sites.

The collection of adherence data to determine the impact on resistance was not included in the WHO strategy and will be prioritized in PEPFAR II. EWIs that measure actual adherence or surrogate markers of adherence will be analyzed and correlated with resistance development. Results from EWIs are used to take action at the site level and make decisions at the national level.

Level 2 is sentinel monitoring of HIVDR among HIV-positive patients who receive first-line ART. A small cohort is established of 100 patients starting first-line ART in sentinel clinics. The cohort is followed for 12 months. Genotyping is performed at baseline, while viral load and repeat genotyping are performed at the 12-month endpoint. Viral load suppression and the presence of mutations are assessed at 12 months. Associated risk factors at the site are evaluated, such as adherence, ARV experience, baseline mutations and drug supply continuity.

Level 3 is surveillance of transmitted HIVDR in newly infected populations. Areas in the country where ART is widely available or scale-up is most rapid are surveyed. Accessible populations are identified, such as pregnant women and IDUs. Surveillance data showed that prevalence of <5% was achieved in five African countries. These data indicate that the incidence and prevalence of transmitted HIVDR are extremely low in these countries.

Efforts are underway to determine whether the WHO strategy can be enhanced to improve current capacity to prevent HIVDR in PEPFAR-supported countries. A 2005 published study documented that mathematical modeling suggested acquired resistance would outweigh the

role of transmitted HIVDR. The position of the multi-agency group was that monitoring of patients on ART should be prioritized rather than transmitted HIVDR.

The multi-agency group identified a number of key questions that should be addressed by research, surveillance or monitoring activities. Research question 1 would focus on empiric first- and second-line regimens that should be used. This question could be answered with a cross-sectional analysis of patients on ART at the time of failure or at 12, 24 or up to 36 months after initiation of therapy. Results from the cross-sectional analysis would include resistance profiles for patients who failed therapy or continued on a failing regimen. Data on the effect of first-line regimens on resistance patterns could be collected as well.

Research question 2 would focus on differences in drug resistance between subtypes and recombinant forms across countries. Sub-questions on this issue would focus on patterns of emergence of resistant mutations that are unique to certain non-B subtypes and the correlation between genotypic and phenotypic resistance in these populations.

Research question 3 would focus on characteristics that increase HIVDR risk. Sub-questions on this issue would focus on the correlation between EWIs and the emergence of HIVDR; a potential association between other program indicators and the emergence of HIVDR; and a possible relationship between informing sites of EWIs and reducing risk.

Research question 4 would focus on the risk of acquisition of HIVDR in pediatric populations. WHO is currently developing a version of the existing strategy for pediatric ART delivery sites. Consideration is being given to creating a strategy for surveying children in different age groups that could reflect resistance patterns over time. PMTCT regimens that are currently being administered might assist in answering research question 4.

Overall, transmitted resistance does not appear to be a major problem at this time despite the massive scale-up of ART in PEPFAR-supported countries. Emergence of resistance must be monitored, particularly in light of the lack of resources for either viral load monitoring or second- and third-line regimens.

CHAC thanked the panelists for providing informative and extensive overviews of the CDC and NIH research and programmatic activities that are underway to better understand and monitor ART resistance in international settings. CHAC advised the agencies to develop a coordinated process if single-dose NVP continues to be used. The members noted that studies have shown the ineffectiveness of various drug combinations to completely prevent the emergence of drug resistance. The members also pointed out that adequate funding should be assured for other drug regimens women will need in international settings for PMTCT.

CHAC Business Session

Ms. Theresa Devlin is an outgoing CHAC member. She provided CHAC with a DVD and other materials that the Alaska Native Tribal Health Consortium recently produced regarding HIV in Alaska Native women. The materials contain positive messages that encourage the strength, self-esteem and sense of community among Alaska Native women. Ms. Devlin urged the federal agencies to take the same approach in targeting communication activities to this population and avoid using negative language to deliver prevention messages.

Dr. Sweet noted that FAPP's four proposed technical solutions to Ryan White reauthorization were distributed to CHAC in writing. CHAC still did not reach consensus on two of FAPP's proposed technical solutions: (1) suspension of penalties to grantees for having >5% in unobligated funds and (2) SONI and client-level data. Dr. Sweet confirmed that the Ryan White Reauthorization Workgroup would further discuss these issue on its next conference call.

Dr. Parham Hopson provided additional details on HRSA's Ryan White reauthorization studies in response to CHAC's earlier request for this information. HRSA conducted six case studies with Parts A-C grantees to determine the impact of changes in the legislation on the provision of core medical services. No impact was observed in the Part C grantees, but Parts A and B grantees requested waivers to provide core medical services in 2007, 2008 and 2009.

The most significant impacts to grantees in providing core medical services under the revised legislation included the administrative burden of tracking dollars, the need to select different contractors, limited service provider capacity, the pressure of responding to changes in both the provision of core medical services and other parts of the law, and challenges in communicating with HAB. HRSA cannot determine the impact of changes in the provision of core medical services on the health and quality of life of clients at this time.

The grantees were required to use funding streams other than Ryan White to assure availability of support services, but communities expressed anxiety, stress and anger with this approach. However, the provision of core medical services in the modified legislation has not been a major issue overall.

HRSA conducted eight case studies through site visits or telephone interviews to determine the impact of funding shifts on Parts A-B grantees. The transition from code-based to name-based data reporting was the reason for the funding shift. Grantees with mature name-based systems received more funding than those with less well-established data systems. The level of service, number of clients and staff decreased at grantee sites that could not leverage other funding sources to maintain services. However, the client demographics of vulnerable or poor persons living with HIV did not change due to the funding shift.

Grantees that received less funding enhanced their monitoring of sub-grantee expenditures and allocated unobligated dollars to other needed areas. In terms of the planning process, Planning Councils were given a larger responsibility, new planning methods were developed, or existing comprehensive plans were modified to be consistent with the current decrease in services.

The grantees made a number of recommendations to HRSA during the site visits and telephone interviews. HRSA should provide grantees with clear, consistent and transparent guidance regarding policies and the funding formula to ensure grant awards are accurately calculated. HRSA should provide grantees with technical assistance on managing different funding streams, collecting and reporting data, and networking and building collaborations.

Dr. Sweet led a discussion on the possibility of CHAC issuing a formal statement to CDC and HRSA to reemphasize its previous recommendation to develop a National HIV Plan. CHAC extensively discussed and made a number of suggestions on potential language to include in or exclude from the statement.

CHAC adopted the following statement by a majority vote of 10 in favor to rename the National HIV Plan and include STDs and other issues.

CHAC supports the development of a *National Strategic Plan for HIV and Other STDs*. CHAC will provide assistance and support in the development of the National Plan. The National Plan will require the interaction of multiple federal agencies to address the needs of the entire population.

CHAC agreed that mental health issues, care and prevention of youth, substance abuse, community involvement and health disparities would be mentioned in the National Plan. CHAC agreed that the statement would include appropriate acknowledgement of and appreciation to CDC and HRSA. CHAC agreed that a member would be assigned to serve on the Strategic Planning Committee. Dr. Sweet confirmed that the draft statement would be circulated to CHAC prior to dissemination to CDC and HRSA.

Dr. Sweet led CHAC in a review of future agenda items that were raised over the course of the meeting. The members proposed placing presentations, overviews or updates of the following topics on future agendas:

- The future direction of CDC's biomedical prevention strategies, including the role of ART in the treatment of patients with diagnosed HIV infection and preexposure prophylaxis in women who choose to become pregnant.
- The future cost to Medicaid, private insurance and the Ryan White HIV/AIDS Program on placing thousands of additional patients on ART earlier in their infection.
- The impact of under-funding of HIV prevention and testing activities on grantees.
- Corrections issues, including standardized HIV testing, workforce shortages and care issues in these settings.
- Update on CDC's prevention activities targeted to the Latino population.
- The importance of funding CDC surveillance and linking this activity to HRSA care.
- Concrete actions the HHS agencies can take collectively, such as the ability of care to lead to prevention and the capacity of prevention messages to lead to care.
- New media, social marketing and other communication strategies CDC and DHAP are using to enhance HIV prevention activities and disseminate messages.

- Inclusion of mental health care in HIV/STD prevention and care: (1) dissemination of SAMHSA funding, including persons who make decisions on allocating dollars, basic resources that should be available at the diagnosis of HIV for mental health care, and mental health interventions for all persons; and (2) increased risk for HIV infection in psychiatric patients.
- Innovative strategies to address stigma.
- The effectiveness of HIV prevention at this time.
- Follow-up discussion on routine HIV testing in CHCs: (1) the rationale for not expanding rapid HIV testing to all CHCs, (2) the number of CHCs that have improved HIV testing, and (3) presentation of data to demonstrate increased HIV testing in CHCs.
- Geographical differences of providing care in rural areas, Southern states and border states versus metropolitan and more fully-funded areas.
- Local flexibility to optimize results versus federally-prescribed measures.
- The role of the community in the medical component, including interventions to improve community-based activities.
- Update on routinization of testing.
- Follow-up on the epidemiology and testing of syphilis.

Dr. Hook confirmed that Rev. Hickman's concern regarding the current agenda would be addressed in developing the May 2009 agenda. Rev. Hickman noted that the current agenda was heavily focused on the biomedical component and did not adequately address community-based or youth issues.

Public Comment Session

Dr. Peter Kerndt, Chair of the National Coalition of STD Directors (NCSD), reported that NCSD is continuing its focus on HIV/STD comorbidity and the need to provide access to clinical and prevention services for STDs. NCSD's recent survey to its membership showed high rates of HIV/STD comorbidity in California, Florida, Indiana, Los Angeles, Massachusetts and San Francisco.

NCSD made several key recommendations for CHAC to consider. CHAC should strengthen its efforts to emphasize the need for targeted STD interventions and ensure that HRSA grantees provide comprehensive STD screening. CHAC should reinvigorate support for the syphilis elimination effort in the most impacted areas as an integral part of the strategy to address disparities and reduce HIV incidence.

CHAC should ask the new Administration to fully fund the implementation of newly issued guidelines in all 65 project areas. CHAC should support the call for DSTDP to be fully funded at \$267 million and for the Surgeon General to launch a targeted, ongoing, comprehensive and committed campaign to combat the staggering rates of STDs in the United States.

Ms. Deborah Arrindell, Vice President of Health Policy for the American Social Health Association (ASHA), reported that ASHA plans to submit policy recommendations to the new Administration. ASHA will urge the Administration to articulate and implement a new and science-based approach to the nation's sexual and reproductive health needs.

ASHA's policy recommendations will ask the new Administration to consider taking action in four important areas: (1) invest in comprehensive sex education; (2) increase funding for DSTDP to \$267 million; (3) direct the Surgeon General to renew the "Call to Action to Promote Sexual Health and Responsible Sexual Behavior;" and (4) increase funding for the CDC Division of Adolescent and School Health to \$66.6 million.

The statements Dr. Kerndt and Ms. Arrindell submitted into the public record are attached to the minutes in their entirety in Appendix I.

Closing Session

CHAC applauded Ms. Margie Scott-Cseh and Ms. Shelley Gordon, CHAC's Committee Management Specialists at CDC and HRSA, respectively, as well as other CDC and HRSA staff for their outstanding efforts in planning and organizing the meeting.

The next CHAC meeting would be held on either May 12-13 or May 19-20, 2009 in Atlanta, Georgia. CDC and HRSA would poll the members by e-mail to determine the exact date.

With no further discussion or business brought before CHAC, Dr. Sweet adjourned the meeting at 2:40 p.m. on November 18, 2008.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Edward W. Hook III, M.D., Co-Chair
CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment

Date

Donna Sweet, M.D., Co-Chair
CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment

APPENDIX I

Statements Submitted Into the Public Record

**Public Comment by The National Coalition of STD Directors
before the
CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
November 18, 2008**

Good afternoon, my name is Dr. Peter Kerndt; I am the Director of the Sexually Transmitted Disease Program for the Los Angeles County Department of Public Health. I am also the current Chair of the National Coalition of STD Directors. I am here today speaking on behalf of the National Coalition of STD Directors, which is a nonprofit, nonpartisan association of STD program directors in 65 CDC directly funded project areas, which include all 50 states, 7 cities and 8 U.S. territories. As the only national organization with a constituency that provides frontline STD services, NCSD appreciates the opportunity to address some of our concerns to the committee.

The connection between STDs and HIV is well recognized. The presence of an STD increases the likelihood of either transmitting or acquiring HIV infection. Sexually transmitted diseases among HIV-positive individuals increase the risk of HIV transmission 2-to-5 times. It is also clear that testing and treatment of STDs can be an effective tool in preventing the spread of HIV.

It is also well known that African Americans are especially disproportionately affected by HIV and STDs. Past CDC supported syphilis elimination efforts have been successful in reducing these disparities and also have likely had an impact on reducing HIV incidence rates. If we are to address health disparities in this country we must do a better job of providing access to clinical and prevention services for STDs.

I would like to share with you some results from a recent survey of some of our members where we explored the connection between HIV and STDs:

- In Massachusetts in 2007, 48% (88/183) of early syphilis among MSMs were HIV infected
- 17% of Florida's 2,070, early syphilis cases reported in 2007 were known to be HIV infected
- In 2007 in California, overall 53% (1,372/2,946) of all early syphilis cases that were interviewed were HIV infected; 30% (415/1,372) of these cases were diagnosed by their HIV care provider

- In January thru October of this year, 183 cases of early syphilis were diagnosed in the state of Indiana; 35% (64) were HIV positive and 55% (35/64) were diagnosed while in care for HIV
- In San Francisco, so far this year, 400 cases of early syphilis have been reported, 2/3 (268) are HIV infected; among those who were HIV infected 60% (161) were diagnosed in HIV care settings. And nearly 40% of all new HIV diagnoses had an STD at the time of their HIV diagnosis
- In Los Angeles, last year over 60% (686/1123) of all MSMs diagnosed with syphilis were HIV infected and nearly a quarter (312-41-12/1,123) were diagnosed in the HIV care setting
- In addition, in Los Angeles, in a 22 month period 43 individuals with acute HIV infection (HIV Ab negative w/ viral loads in the 100,000's+) were identified; nearly 60% were co-infected with syphilis, GC or CT at one or more sites at the time of their acute HIV diagnosis. Suggesting that most acquired their HIV infection at the time they contracted their STD

We can only speculate how many of the new syphilis cases (esp. P&S syphilis cases) that are diagnosed and that test HIV positive for the first time are actually new HIV infections that were acquired at the time they acquired syphilis. STD co-infection in the acute stage of HIV infection is common. Any MSM with an STD and a negative HIV Ab test should, in most instances, be evaluated to rule out acute HIV infection.

Furthermore, there is an enormous burden of STDs in HIV care settings that if left undiagnosed and untreated is a missed prevention opportunity that has and will likely contribute substantially to the continued high and unacceptable levels of HIV incidence.

NCSA urges the CHAC to redouble your efforts to bring attention to the need for targeted interventions for this setting, ensuring that HRSA funded care settings are providing comprehensive STD screening (for all appropriate sites -- rectal, urethral and oral). NCSA also urges CHAC to reinvigorate support for syphilis elimination efforts in those areas most affected as an integral part of the strategy to address disparities and to reduce HIV incidence.

Last month, after a two year comprehensive review process that included input from all stakeholders, CDC issued revised guidelines for HIV/STD Partner Services for state and local health jurisdictions. NCSA urges CHAC to advocate for, and the new Administration to fully fund, the implementation of these newly issued guidelines in all 65 project areas.

We also strongly support the call of our partner organization, ASHA, that the Division of STD Prevention at CDC should be fully funded at \$267 million and that the Surgeon General should launch a targeted ongoing comprehensive and committed campaign to combat the staggering rates of STDs in this country. The Surgeon General should address these public health crises in conjunction with the development of a broader, comprehensive, domestic HIV/AIDS strategy

that includes full implementation of partner services, interventions that target the HIV care setting and strategies to identify and prevent acute HIV infections.

Past funding cuts have compromised core STD services and the ability of STD Directors to effectively prevent and control the spread of HIV and STDs. However, we are hopeful that with a renewed commitment and focus on these issues, along with more integrated approaches and evidence-based prevention strategies, progress can be made to improve the reproductive health of all Americans and control the domestic STD/HIV epidemic.

Thank you and we request that this statement be included in the record.

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**Statement of the American Social Health Association
Before the
CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
November 2008**

Good morning, I am Deborah Arrindell, Vice President of Health Policy, of the American Social Health Association (ASHA), a nonprofit, nonpartisan organization. Since 1914 ASHA has sought to eliminate sexually transmitted infections (STIs) and their harmful consequences for individuals, families and communities. I appreciate the opportunity to address the Committee.

We appreciate the daunting tasks in STD-HIV prevention and treatment that this Committee must address and we appreciate your leadership. Today we want to share some of the policy considerations we will be asking President-elect Obama's Administration to address. The new Administration will have the opportunity to advance a reproductive and sexual health agenda that will make a profound difference in the lives and health of women, men, and families in our nation. The United States has the highest rates of sexually transmitted infections of any industrialized nation. Approximately 19 million new cases of STIs occur each year. STIs take their heaviest toll on women, teenagers, and people of color.

The American Social Health Association will urge the administration to articulate and implement a new, science-based approach to the nation's sexual and reproductive health needs. We believe concrete efforts are essential in the following areas:

- **Invest in Comprehensive Sex Education.** Complete, accurate, and age-appropriate sex education helps young people reduce their risk of unintended pregnancies and STIs, including HIV/AIDS. Sex education programs that include information about both abstinence and contraception help keep young people safe by delaying sexual activity and increasing contraceptive use when they do have sex. Most parents believe that young people should receive comprehensive sex education, as do a broad range of professional health organizations including the American Public Health Association, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Medical Association. Currently, the United States has no federal sex education program. We will urge the President to invest in the lives and health of our nation's young people by providing at least \$50 million to promote comprehensive sex education in our schools nationwide in his first budget submitted to Congress.
- **Increase Funding for the Centers for Disease Control and Prevention's (CDC) STD Prevention Program to \$267 million.** Approximately 19 million new cases of STIs occur each year, giving the United States some of the highest rates of STIs of any industrialized nation. Young people are at particularly high risk, comprising nearly 50 percent of all new STIs each year. Women are especially threatened: they are more easily infected, less likely to show symptoms, and more likely to suffer long-term consequences such as pelvic inflammatory disease, infertility, ectopic pregnancy, and

cervical cancer. Across STIS there are staggering racial disparities that must be addressed. Despite these startling statistics and grave risks, base STI program funding levels have remained frozen for more than a decade. Of particular importance is CDC's Infertility Prevention Program, which is an STI success story. In the areas where it has been implemented, rates of chlamydia - the leading cause of infertility in the United States - have significantly diminished. Current funding for STI prevention is approximately \$157 million. We urge the President to include \$267 million for CDC's STI prevention programs in the first budget he submits to Congress.

- **Direct the Surgeon General to Renew the “Call to Action to Promote Sexual Health and Responsible Sexual Behavior.”** The Surgeon General should mobilize public support for science-based approaches to sexual health in a renewed Call to Action. This Call to Action should build upon the 2001 Call from then-Surgeon General David Satcher; which sought to engage the public in a thoughtful discussion about sexuality. The new Call to Action should acknowledge the positive aspects of sexuality as well as address a broad range of sexual health issues, including STIs, HIV/AIDS, and unintended pregnancy. It should acknowledge that sex education must be age-appropriate and evidence-based. In addition, the Surgeon General should launch a targeted campaign to combat the staggering rates of STIs in this country. The Surgeon General should address these public health crises in conjunction with the development of a broader, comprehensive, domestic HIV/AIDS strategy.
- **Increase Funding for CDC’s Division of Adolescent and School Health (DASH) to \$66.6 million.** DASH plays a critical role in promoting evidence-based behavioral health interventions with strong programs in HIV and STI prevention. The CDC should tighten eligibility requirements to guarantee that funding is barred from entities that provide misleading information about reproductive health and to ensure better integration with school-based health centers. Current funding is \$40.2 million. We urge the President to include \$66.6 million for DASH in his first budget submitted to Congress.

Thank you again for the opportunity to speak to the committee. We hope you will call on ASHA if we can be helpful to you in any way. I ask that this statement be included in the record of this meeting.

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